No. 84-267

IN THE SUPREME COURT OF THE
UNITED STATES
October Term, 1984

William P. Clark, et al.,
Petitioners,
v.
Southern Oregon Citizens Against
Toxic Sprays, Inc.

ON PETITION FOR A WRIT OF
CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR
THE NINTH CIRCUIT

AMICUS BRIEF OF PAUL MERRELL AND SAVE OUR ecoSYSTEMS, INC., IN OPPOSITION TO PETITION FOR CERTIORARI

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QUESTION PRESENTED

Whether 40 C.F.R. § 1502.22(b) requires the Bureau of Land Management (BLM) to prepare a worst case analysis of the effects of using herbicides on BLM lands when there is scientific uncertainty concerning the effects of those herbicides on human health.

AMICUS PARTIES

Paul Merrell is an inholder in the Siuslaw National Forest. He successfully represented himself in a suit against the Forest Service, the BLM and EPA over the use of herbicides in the valley where he resides. The case took his full time for over two years. When the government appealed the district court's decision, Michael Axline, one of the attorneys submitting this amicus brief, represented Mr. Merrell before the Ninth Circuit. The Ninth Circuit affirmed the district court's decision in Merrell v. Block, Nos. 83-3887, 83-3916 (9th Cir. Jan. 27, 1984) (petition for rehearing pending). Merrell and his family have suffered extensive injuries as a result of herbicide use by federal land management agencies on property adjoining their property. Carol Merrell

suffered two separate miscarriages shortly after two separate incidents of exposure to herbicides.

Save Our ecoSystems is a small, non-profit, Oregon corporation dedicated to improving the quality of the environment. It successfully sued in federal district court when the BLM, as a result of the court's opinion in the instant case, prepared what the BLM called a "worst case analysis" (actually a "best case analysis"). The government also appealed this decision to the Ninth Circuit. The case was jointly argued with Merrell v. Block, supra, and the Ninth Circuit affirmed the district court. Save Our ecoSystems v. Clark, Nos. 83-3908, 83-3918 (9th Cir. Jan. 27, 1984) (joint opinion with Merrell v. Block). The interests of amicus parties are directly affected by the Petition filed by the government in the instant case.

Paul Merrell filed an amicus brief before the Ninth Circuit in this case. Petitioners and Respondents have consented to the filing of this amicus brief (see Appendix A, attached).

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes and Regulations

Miscellaneous

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I. STATEMENT OF THE CASE

This case involves the application of a straightforward and unambiguous regulation, 40 C.F.R. § 1502.22(b), to an uncontested set of facts. The Circuits of the United States Court of Appeals are in agreement as to the proper interpretation of 40 C.F.R. § 1502.22(b).[1/]

40 C.F.R. § 1502.22 is a regulation of the Council on Environmental Quality (CEQ).[2/] 40 C.F.R. § 1502.22(b) directs

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1/ The Ninth Circuit in this case stated: "[40 C.F.R.] § 1502.22 is not difficult to interpret. It is straightforward and means what it says." Petitioners' Appendix at 11a. See also Sierra Club v. Sigler, 695 F.2d 957, 973 (5th Cir. 1983) ("This regulation is quite straightforward"). The Petitioners did not appeal the District Court's factual findings. See Petitioners' Appendix at 4a.

2/ The CEQ's regulations implement the National Environmental Policy Act (NEPA), 42 U.S.C. § 4321 et seq., are

agencies to prepare a "worst case analysis" of environmental consequences when considering whether to proceed with a proposal in the face of uncertainty about the proposal's environmental effects. The uncertainty here is whether the use of herbicides by the BLM will cause cancer, birth defects, and gene mutations among exposed humans.

It is uncontested that there is scientific uncertainty regarding the human health effects of the herbicides which the BLM proposes to spray. The District Court, the Ninth Circuit, Plaintiff's witnesses, and Petitioners' own witnesses agreed, for example, that there is evidence that the herbicide 2,4-D is a carcinogen. The Petitioners'

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binding on all federal agencies and are "entitled to substantial deference." Andrus v. Sierra Club, 442 U.S. 347, 357 (1979). Petitioners do not challenge the validity of 40 C.F.R. § 1502.22.

expert, Dr. Dost (a veterinarian), testified to the existence of studies (with which he disagreed) suggesting that 2,4-D causes cancer. Dr. Dost also recognized:

> There is presently valid scientific disagreement on the applicability of the threshold concept in assessing the dose necessary to initiate cancer. The reason is that cancer is a proliferative disease, and it is argued by some that any dose of a carcinogen, no matter how minute has some finite probability of causing cancer.

Petitioners' Appendix at 21a (emphasis added).

The "valid scientific disagreement" referred to by Dr. Dost consists primarily of Dr. Dost disagreeing with the rest of the scientific community in the United States, including the National Academy of Sciences,[3/] the National Can-

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[3/] The National Academy of Sciences has observed: "[T]he no effect level is

cer Institute, and the federal government's Interagency Regulatory Liaison Group about the propriety of establishing threshold levels below which a carcinogen can be expected to have no impacts.[4/]

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statistically meaningless and therefore of limited value since it merely means that no effect was observed in studies using a group of animals of a particular size. Such an observation is completely compatible with the presence of an adverse effect . . ." National Academy of Sciences, Principles for Evaluating Chemicals in the Environment, at 83 (Washington, D.C. 1975).

4/ According to the Interagency Regulatory Liaison Group (IRLG): "There is presently no acceptable way to determine reliably a threshold for a carcinogen for an entire population." 44 Fed. Reg. 39,858, 39,876 (Friday, July 6, 1979). The IRLG is composed of scientists from the EPA, the Food and Drug Administration, the Consumer Product Safety Commission and the Occupational Safety and Health Administration, as well as senior scientists at the National Cancer Institute and the National Institute of Environmental Health Sciences. The report reflects their "best judgment . . . on the scientific concepts and methods currently in use to identify and evaluate substances that may pose a risk of cancer to humans." Id. See also Leape,

Because the uncontested evidence introduced at trial reveals significant scientific uncertainty about the effects on human health of the herbicides which the BLM proposes to use, the lower courts properly concluded that the BLM must prepare a worst case analysis in accordance with 40 C.F.R. § 1502.22(b).[5/]

"Quantitative Risk Assessment in Regulation of Environmental Carcinogens," 4 Harv. Env'tl L. Rev. 86, 100 (1980) (It is . . . widely agreed that, at least when formulating public health policies, one should assume that there are no thresholds or 'safe' doses.")

5/ 40 C.F.R. § 1502.22 provides:

> When an agency is evaluating significant adverse effects on the human environment . . . and there are gaps in relevant information or scientific uncertainty, the agency shall always make clear that such information is lacking or that uncertainty exists.
>
> . . . .
>
> (b) If (1) the information

II. REASONS FOR DENYING THE PETITION

Petitioners' objections to the decision of the Ninth Circuit rest on two assertions: (1) NEPA does not

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> relevant to adverse impacts is essential to a reasoned choice among alternatives and is not known and the overall costs of obtaining it are exorbitant or (2) the information relevant to adverse impacts is important to the decision and the means to obtain it are not known (e.g., the means for obtaining it are beyond the state of the art) the agency shall weigh the need for the action against the risk and severity of possible adverse impacts were the action to proceed in the face of uncertainty. If the agency proceeds, it shall include a worst case analysis and an indication of the probability or improbability of its occurrence.

40 C.F.R. § 1502.22 codifies prior NEPA case law requiring agencies to disclose and examine uncertainties about the effects of their proposals. See Sierra Club v. Sigler, 695 F.2d 957, 971 (5th Cir. 1983) (en banc) ("The CEQ's regulation merely codifies these judicially created principles").

require "completely hypothetical worst case scenarios" and Plaintiffs have not demonstrated a risk that the worst case will actually occur (Petition at 8); and (2) the BLM should be excused from its NEPA duties because the EPA has conditionally registered the subject herbicides under the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136 et seq. (FIFRA). The first assertion ignores the record in this case, the purposes of NEPA generally, and the purposes of 40 C.F.R. § 1502.22(b) in particular. The second assertion ignores the purposes and limitations of the FIFRA registration process. The lower courts have uniformly rejected Petitioners' arguments over a period of seven years.

A. Plaintiff Has Demonstrated A Risk Adverse Health Effects Will Occur.

Both the District Court and the Court of Appeals found that the BLM's proposal to spray herbicides created serious health risks. Nevertheless, Petitioners contend in this Court that because: "there is no credible scientific evidence that 2,4-D or any of the other proposed herbicides has any carcinogenic effects," no worst case analysis need be prepared. Petition at 11. Petitioners' bald statement that there is no scientific evidence suggesting that the herbicides at issue might affect human health is flatly contradicted by the actions of EPA, by the record, by the opinion of the District Court, and by the opinion of the Court of Appeals. The District Court found that at least three studies indicate that 2,4-D causes cancer.[6/] EPA itself

has, on the basis of these studies, ordered the preparation of additional studies of the carcinogenic and other effects of 2,4-D. Appendix B. The record clearly shows that, at a minimum, there is scientific uncertainty about the effects of 2,4-D. The Petitioners ignore, rather than rebut, this overwhelming evidence.

More fundamentally, Petitioners' demands for proof of cancer-causation distort 40 C.F.R. § 1502.22(b)'s purpose and triggering provisions. It is not necessary to prove that the proposed use of herbicides will cause cancer, birth defects or gene mutations before the BLM must assess the problem and prepare a worst case analysis under 40 C.F.R.

6/ See Petitioners' Appendix at 22a-23a (opinion of District Court citing studies by Dr. Reuber, a Russian study and Swedish studies).

§ 1502.22(b). It is only necessary to demonstrate that there is sufficient disagreement in the scientific community regarding the carcinogenic and mutagenic properties of these herbicides. If credible scientists believe these herbicides cause or may cause cancer and birth defects, Petitioners must discuss in an EIS the possibility that these scientists might be correct.

Petitioners' fear that agencies will be forced to concern themselves with an array of "phantasmagorical" disasters (Petition at 11) is, as the Ninth Circuit put it, largely "self-induced." Petitioners' Appendix at 11a. 40 C.F.R. § 1502.22(b) contains two precise and reasonable standards for determining which uncertainties are sufficiently important to compel a worst case analysis. Before a worst case analysis must be prepared, (1) the

potential effects must be significant,[7] and (2) the uncertainties must be serious enough to make consideration of those uncertainties essential to a reasoned decision.

Petitioners do not challenge the district court's finding of fact that these two tests were met.[8] Rather,

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[7] Both courts below correctly concluded that the environmental effects in question here --cancer, birth defects, and gene mutations-- are "significant." See Petitioners' Appendix at 6a (Ninth Circuit Opinion); Petitioners' Appendix at 20a (District Court Opinion). See generally 40 C.F.R. § 1508.27 (effect on "public health and safety" is one factor in determining significance); CATS v. Bergland, 428 F. Supp. 908, 927 (D. Ore. 1977) ("no subject to be covered by an EIS can be more important than the potential effects of a federal program upon the health of human beings.")

[8] Petitioners do criticize the district court for deciding the case "solely" on the basis of expert testimony, Petition at 11, note 10, and claim that "[c]ourts are hardly well suited for making such judgments after a trial." Petition at 11, note 10. Perhaps Petitioners would have preferred

they claim that the potential effects are too remote to warrant consideration because no "'real possibility of the occurrence has been proved.'" Petition at 11, quoting Sierra Club v. Sigler, 695 F.2d at 975 n.14 (emphasis by Petitioners). Plaintiff's evidence at trial, however, clearly established the real possibility that adverse health effects will follow from herbicide exposure. Evidence in the record supporting this conclusion includes: (1) affidavits of Ruth Shearer, a genetic toxicologist, reviewing studies which sug-

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that the court decide the case based on lay testimony and without a trial. Petitioners' arguments are frivolous. Expert testimony at trial is the best conceivable basis for the district court's decision. Moreover, the district court did not have to resolve controversy based on the technical merits of the expert's positions, it only had to find that there was sufficient disagreement between scientists to warrant a worst case analysis. Courts are ideally suited for such a task.

gest that phenoxy herbicides cause serious health effects, including cancer; (2) the affidavit of the BLM's own expert Dr. Dost, stating in part: "There is presently valid scientific disagreement on the applicability of the threshold concept in assessing the dose necessary to initiate cancer . . ." (3) the recommendation of the Scientific Advisory Panel to the EPA that further tests of the oncogenicity (tumor promotion) of 2,4-D be conducted, (4) evidence that EPA is in fact reviewing the effects of 2,4-D (affidavit of Ruth Shearer) (see also Appendix B to the brief); and (5) the testimony of Dr. Reuber, and the Swedish and Russian studies cited in footnote 6, supra.

But Petitioners still are not satisfied. In essence they demand proof, rather than a real possibility, that these effects will occur. This added

element amounts to imposing on plaintiffs the burden of proving causation. Such a requirement is inappropriate where the scientific uncertainty concerns precisely the causation issue. In responding to this argument, the Ninth Circuit wrote:

> The BLM's belief that its herbicides are safe does not relieve it from discussing the possibility that they are not, when its own experts admit that there is substantial uncertainty. When uncertainty exists, it must be exposed.

Petitioners' Appendix at 7a (emphasis in original). Petitioners' demand for proof of causation as a prerequisite to preparing a worst case analysis is particularly inappropriate when such proof is not a prerequisite for considering impacts in EISs generally. Agencies cannot limit their inquiry to effects that are certain to follow from a pro-

posed action. They must also examine effects which may be caused by the proposal. See Metropolitan Edison Co. v. People Against Nuclear Energy, U.S. ____, 103 S. Ct. 1556, 1561 (1983) ("Another effect of renewed operation [of a nuclear plant] is a risk of a nuclear accident) (emphasis added); Scientists Institute for Public Information, Inc. v. Atomic Energy Commission, 481 F.2d 1079, 1092 (D.C. Cir. 1973) ("Reasonable forecasting and speculation is thus implicit in NEPA . . .").

Issues of possibility, probability, and remoteness must be considered under 40 C.F.R. §1502.22(b), but only after the worst case analysis is prepared. 40 C.F.R. § 1502.22(b) provides: "If the agency proceeds [in the face of uncertainty] it shall include a worst case anlysis and an indication of the probability or improbability of its occur-

rence." (Emphasis added). According to the plain language of 40 C.F.R. § 1502.22(b), the likelihood of occurrence is not a threshold factor in determining whether a worst case analysis is required.[9] Petitioners overlook this language in their attempt to put the cart of government discretion before the horse of public disclosure of health information.[10]

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[9] See Sierra Club v. Sigler, supra 695 F.2d at 974 ("as to remoteness, the triggering provisions do not use it as a criterion"); Village of False Pass v. Watt, 595 F. Supp. 1123, 1152 (D. Alaska 1983).

[10] None of the four cases cited by Petitioners in support of their remoteness argument address 40 C.F.R. § 1502.22. Two of the cases involved consequences only distantly related to the agency action. See Environmental Defense Fund, Inc. v. Hoffman, 566 F.2d 1060, 1067 (5th Cir. 1977) (effect of dam on agricultural use of groundwater); Trout Unlimited v. Morton, 509 F.2d 1267, 1284 (9th Cir. 1974) (effect of dam on second home development in locality). A third case concerned alternatives to a proposal, not its consequen-

The CEQ's interpretation of its own regulation also rebuts Petitioners' argument. In responding to comments on a draft of the regulations the CEQ stated:

> Several commenters expressed concern that this requirement [for a worst case analysis] would place undue emphasis on the possible occurrence of adverse environmental consequences regardless of how remote the possibility might be. In response, the Council added a phrase designed to ensure that the improbability as well as the probability of adverse environmental consequences would be discussed in worst case analyses under this section.

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ces. See NRDC v. Morton, 458 F.2d 827, 836-37 (D.C. Cir. 1972) (rejecting claim that agency must consider alternative national energy policies, such as oil shale development, before granting offshore oil and gas leases). In the final case (the only one decided after the enactment of 40 C.F.R. § 1502.22), the agency effectively eliminated the uncertainty by commissioning an extensive study of the dangers of building a dam near a fault system. See Warm Springs Dam Task Force v. Gribble, 621 F.2d 1017, 1026 (9th Cir. 1980).

43 Fed. Reg. 55,978, 55,984 (Wednesday, November 29, 1978) (emphasis added). The District Court and the Ninth Circuit properly found that the record in this case demonstrates the need for a worst case analysis under 40 C.F.R. § 1502.22(b). There is, therefore, no reason for issuing a Writ of Certiorari.

B. Registration of Herbicides Under The Federal Insecticide, Fungicide, And Rodenticide Act (FIFRA) Does Not Relieve The BLM of its NEPA Obligations.

Petitioners argue that 40 C.F.R. § 1502.22(b) should not apply to BLM decisions to spray herbicides because herbicides are registered for marketing in the United States by the EPA, pursuant to FIFRA. Petitioners do not disclose that all of the herbicides at issue in this case are conditionally registered and require additional information as to their safety before they

may be fully registered under FIFRA. The Petitioners' registration argument, therefore, is irrelevant to this case, which does not involve any chemicals which have been registered on the basis of information required by FIFRA. Even if the chemicals involved were fully registered, Petitioners do not discuss the type of anlaysis performed by EPA prior to registering herbicides, or explain why such an analysis might satisfy another agency's NEPA obligations. Nevertheless, Petitioners seek permission to rely on EPA's registration to avoid their obligations under 40 C.F.R. § 1502.22(b).

EPA's registration of herbicides under FIFRA does not involve many of the considerations required by NEPA. Certainly EPA's registration of herbicides under FIFRA does not involve preparation of a worst case analysis. Petitioners'

argument that requiring a worst case analysis will require substantial duplication of agency effort is factually incorrect, was not raised below, and rests upon 40 C.F.R. § 1502.22(a), which is not at issue in this case.

1. The Herbicides BLM Proposes to Use Are Conditionally Registered Because of Incomplete Data On Their Effects.

FIFRA provides for "conditional registration" of chemicals where the data necessary to satisfy FIFRA's registration standards has not yet been generated. See 7 U.S.C. § 136a(c)(7)(C) ("The Administrator may conditionally register a pesticide . . . for a period reasonably sufficient for the generation and submission of required data . . ."). For chemicals registered prior to the 1978 amendments to FIFRA (which imposed additional safety information

requirements on previously registered pesticides), registrations may continue pending the completion of new studies. See 7 U.S.C. § 136a(c)(2)(B). Each of the herbicides at issue in this case is registered under one of these provisions, and by definition, therefore, EPA lacks information necessary to fully register them. See Appendix B (data call in for 2,4-D); Save Our ecoSystems v. Clark, Civ. No. 83-3908 (Ninth Cir. Jan. 27, 1984)) (petition for rehearing pending) (Slip Op. at 11, 23 note 9).

It is not necessary in this case to reach the question of whether the Petitioners may rely upon EPA's consideration of the impacts on human health of registered chemicals because the uncontested evidence shows that EPA itself is still in the process of considering the human health impacts of these chemicals. There is legitimate scientific

uncertainty concerning the risks posed by the proposed herbicides, EPA has not resolved the uncertainty or prepared a worst case analysis, and the Petitioners therefore may not rely on EPA's "registration" as an excuse for not preparing a worst case analysis.

2. The Standard For Registering Chemicals Under FIFRA Is Not Safety, But Whether Benefits Exceed Costs.

Under FIFRA, pesticides may be registered for commercial marketing in the United States if they "will not generally cause unreasonable adverse effects on the environment." 7 U.S.C. § 136a(c)(5)(D). FIFRA defines "unreasonable adverse effects on the environment" as: "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any

pesticide." 7 U.S.C. § 136(bb). Petitioners accurately describe the shortcoming of the standard: "Obviously, EPA's registration of an herbicide is not a guarantee of safety to either man or the environment." Petition at 15. Petitioners go on to state: "We recognize that in some cases a substance will be registered, even though it is known to cause serious environmental effects, on the basis that the benefits outweigh the risks." Id. This is a remarkably frank admission in this Court, and contradicts the Petitioners' position below.

Petitioners' statements to this Court should be contrasted with their policy regarding the public discussion of safety issues in EISs. That policy is:

> [t]opics which address issues of herbicide toxicity and/or human health effects should be

> avoided. Such subject matter is more appropriately discussed by expertise in other federal or state agencies. Simply stated, our position is: that so long as herbicides are registered and approved for forestry use by EPA, BLM may appropriately use such chemicals within specified procedural safeguards.

BLM Field Guide to Policies and Procedures Required For Vegetation Management with Herbicides In Western Oregon (quoted in Save Our ecoSystems v. Clark, supra, Slip Op. at 23, n.8). Petitioners thus have a policy against disclosing or discussing in EISs issues relating to the safety of the herbicides they propose to use.[11/] In short, although

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11/ Petitioners predict that a worst case analysis of 2,4-D's health effects will "merely mislead and confuse both decisionmakers and the public." Petition at 16. Petitioners apparently feel that the public must be protected from information on the possible dangers of these chemicals. This condescending attitude robs individuals of the opportunity to judge the evidence for themselves and make their personal decisions

Petitioners admit before this Court that registration is no guarantee of safety, it is their policy to respond to the public's questions about safety by treating the registration process as if it did guarantee safety. Preparing a worst case analysis will force Petitioners to abandon this deception.

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accordingly. Moreover, it further insulates the BLM from public scrutiny of the merits of its herbicide program. This Court has observed with regard to public disclosure of information generated through FIFRA registration:

> [P]ublic disclosure can provide an effective check on the decisionmaking processes of EPA and allows members of the public to determine the likelihood of individualized risks peculiar to their use of [or exposure to] the product.

Ruckelshaus v. Monsanto Co., ____ U.S. ____, 104 S. Ct. 2862, 2880 (1984).

3. EPA Is Not Required By FIFRA to Include a Worst Case Analysis In the Registration Process.

Nothing in FIFRA requires preparation of a worst case analysis by EPA prior to the registration of a pesticide. See generally 7 U.S.C. §§ 136-136y. Even if EPA included a worst case analysis in its registration process, the secrecy of that process would prevent reliance on EPA's registration by other agencies. Until the decision of this Court in Ruckelshaus v. Monsanto Co., _____ U.S. _____, 104 S. Ct. 2862 (1984), the chemical industry had successfully prevented public release by EPA of data submitted in support of registration. For a worst case analysis to perform its intended function, however, it must reveal the worst case to the public and to the decisionmakers. The unavailability of EPA's registration

information precluded consideration of the information by the public and decisionmakers.

Agencies are specifically prohibited from relying in EISs on proprietary data unavailable to the public (40 C.F.R. § 1502.21). Adopting Petitioners' position would result in the anomaly that, although Petitioners may not rely on non-public proprietary information in their EISs, they may rely on such information if it is in the (exclusive) possession of another agency. Even releasing information submitted in support of registration will not substitute for the preparation of a worst case analysis, however, since information submitted in support of registration does not disclose worst case scenarios.

4. Preparation of a Worst Case Analysis Will Not Result In a Duplication of Effort.

In Oregon Environmental Council v. Kunzman, 714 F.2d 901 (9th Cir. 1983), the court refused to allow the Department of Agriculture to rely on the fact that a chemical had been registered by EPA to avoid discussing the health risks of spraying that chemical in a populated area. The Ninth Circuit in the instant case applied that decision to rebut Petitioners' argument that FIFRA registration removes the need for examining an herbicide's safety. Petitioners now argue, without any supporting facts, precedent or analysis, that applying 40 C.F.R. § 1502.22 to the use of herbicides will result in duplication of effort and unnecessary expenditures of funds.

Petitioners raise this argument in

the wrong case. The Ninth Circuit in this case merely ordered preparation of a worst case analysis (something EPA has not prepared and which therefore would not "duplicate" anything). The court did not order in this case "independent research on the health effects . . . of herbicides." Petition at 20. Although the Ninth Circuit did order such research, pursuant to 40 C.F.R. § 1502.22(a), in Save Our ecoSystems, supra, that case is not before the Court. Petitioners' concern about research is merely an attempt to divert attention from the fact that they have steadfastly refused to discuss even the information on adverse health effects that they already have or can easily obtain. There can be no other meaning to the Petitioners' Field Guide, quoted supra, than that discussions of herbicides' effects on human health "should

be avoided."

A worst case analysis is actually intended to avoid the duplication Petitioners fear, by acting as a safety valve when the cost of doing research is "exorbitant." See 40 C.F.R. § 1502.22(a). A worst case analysis does not require millions of dollars in research. It simply requires disclosure of possible worst case scenarios and consideration of whether it is likely these scenarios will occur. Petitioners' argument that the Ninth Circuit's ruling in this case will result in duplication of effort and the expenditure of enormous sums (there is absolutely no evidence of this in the record, since it was not argued below in this case) is contrary to the plain language of 40 C.F.R. § 1502.22, which allows preparation of a worst case analysis as a means of avoiding exorbitant costs.

CONCLUSION

Lower courts are in agreement that 40 C.F.R. § 1502.22 is a simple, straightforward regulation that applies to the facts of this case. Petitioners have not demonstrated a conflict among Circuits nor any compelling reason to grant a Writ of Certiorari in this case. Amicus parties therefore request that the Petition for Writ of Certiorari be denied.

Respectfully submitted,

Michael Axline
Counsel for Plaintiffs

ON THE BRIEF
Will Whelan
Legal Intern

Dated this 29th day of October, 1984.

APPENDIX A

ORDER AND NOTICE

Dear Registrant:

EPA recently completed a review of the available scientific information on the potential health effects of 2,4-D.

On April 29, 1980, based on the findings of the review, the Agency announced that significant gaps exist in the data base for 2,4-D and that additional scientific information will be required from the registrants under Section 3(c)(2)(B) of Federal Insecticide Fungicide Rodenticide Act (FIFRA), 7 U.S.C. 136a(c)(2)(B). This provision allows the Administrator of EPA to request any additional data from

pesticide registrants that is considered necessary to maintain the registration of existing products. . . .

. . . .

II. WHAT DATA ARE NEEDED

EPA has determined that significant gaps exist in the data base for pesticides containing 2,4-D compounds. In order to make further determinations concerning potential health effects of 2,4-D, the Agency has determined that data from the studies listed below are required to support the continued registration of all products containing the various forms of 2,4-D. The required studies must be conducted in accordance with the referenced sections of EPA's proposed pesticide registration guidelines, or other approved test standards such as those which are adopted by the Organization for Economic Cooperation

and Development (OECD) except as modified or supplemented below.

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DATA REQUIREMENTS

1. Oncogenicity studies

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2. Reproduction study

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3. Teratogenicity studies

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4. Neurotoxicity studies

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5. Metabolism studies

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6. Acute oral toxicity studies

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7. Acute dermal toxicity studies

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8. Dermal absorption studies

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Sincerely yours,

Edwin L. Johnson
Deputy Assistant
Administrator for
Pesticide Programs